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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/077,054	02/12/2002	Jonathan C. Makielski	960296.98032	1596

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EXAMINER

GALVEZ, JAMES JASON

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 09/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/077,054

Applicant(s)

MAKIELSKI ET AL.

Examiner

J. Jason Galvez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/11/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 1,8 and 10-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-7 and 9 is/are rejected.
- 7) ☒ Claim(s) 7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/12/2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/16/02</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election with traverse of invention I in the reply filed on 8/3/2004 is acknowledged. The traversal is on the ground(s) that examining and
5 searching the inventions I-III and V-VI together would not confer an undue burden on the examiner. This is not found persuasive because the inventions represent different products and/or different methods and therefore would require different search strategies and ultimately different searches all together. In addition, the different inventions are classified in different classes and
10 subclasses, further supporting that examining the inventions together would result in an undue burden on the Examiner and USPTO resources. In the instant application claims 1-15 are pending, of which 1, 8, and 11-15 are withdrawn from consideration and 2-7 and 9 are under consideration.

The requirement is still deemed proper and is therefore made FINAL.

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Specification Objections

The use of the trademarks Clontech®, Invitrogen®, Qiagen®, Excite®, and Stratagene® have been noted in this application (pp. 9-11). They should be capitalized where ever they appear.

20 Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

Claim Objections

Claim 7 is objected to because of the following informalities: "at least one of a codon" should read at least one codon. Appropriate correction is required.

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Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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Claims 5 and 6 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 5 and 6 are drawn to a cultured cell with no indication of the cell being isolated in any fashion, therefore the claims could encompass non-statutory subject manner, such as cloned humans.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

20

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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The factors under consideration in regards to whether or not enablement requirements have been met are summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the

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art, and the breath of claims. *Ex Parte Forman*, (230 USPQ 546 (Bd. Pat. App. & Int. 1986)); *In re Wands*, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Claims 2, 3, 5, 6, and 9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID No. 1, does not

5 reasonably provide enablement for SEQ ID No. 1 encoding for a “conservative substitution, deletion or rearrangement at one or more non-critical amino acid position”. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Polynucleotides encoding

10 for a “conservative substitution, deletion or rearrangement” is a broad claim that may or may not contain polynucleotide sequences that would operate within the framework of the present invention. Even conservative substitutions can result in a marked decrease in function [Luck et al., Mol Endocrinol., 1991 Dec;5(12):1880-6, see abstract]. In light of Luck et al., it would be impossible to

15 practice the claimed invention commensurate in scope due to the quantity of experimentation necessary, the level of unpredictability in the art, the absence of adequate working examples, the nature of invention, and the breadth of the claims. In addition the invention is not commensurate in scope because it would require undue experimentation to figure out what amino positions are “non-

20 critical” based on the level of unpredictability in the art and the lack of working examples in the disclosure.

Claims 2, 3, 5-7, and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s)

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contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 2, 3, 5, 6, and 9 are drawn to polynucleotides encoding a
5 “conservative substitution, deletion or rearrangement at one or more non-critical amino acid position”, and a method using said polynucleotides. The claims do not require that the polynucleotides encode a polypeptide having any particular biological activity, structure, or function and therefore provide no identifying characteristics of the claimed polynucleotide genus. To provide adequate written
10 description and evidence of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. Since there
15 is no required structure, properties, or functions, a person of ordinary skill in the art cannot envision the claimed polynucleotide genus. Thus, only the isolated polynucleotides set forth in SEQ ID No. 1, but not the full breadth of the claims meet the written description provision of 35 U.S.C. § 112, 1st paragraph.

Claim 7 is drawn to a polynucleotide “comprising at least 20 contiguous
20 nucleotides of SEQ ID No. 1” and further limited to specific regions of the claimed polynucleotide. This claim could conceivably encompass many more nucleotides than the “at least 20” being claimed, which are not disclosed. Thus, only the isolated polynucleotides, including partial sequences, set forth in SEQ ID No. 1,

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but not the full breadth of the claim meets the written description provision of 35 U.S.C. § 112, 1st paragraph.

Claim Rejections - 35 USC § 112

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

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Claims 4 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 4 is drawn to a polynucleotide linked to a “non-native expression control sequence”. The claim is rendered indefinite because it is not clear what the term “non-native” means and/or what the term could encompass.

Additionally, it is not clear what means of “control” are intended to be used.

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Claim 7 is drawn to SED ID No. 1, including “a codon that encodes amino acid 558 and a codon that encodes amino acid 618”. It is not entirely clear what is being claimed. For examination purposes it has been assumed that amino acids referred correspond to SEQ ID No. 2. It would be remedial if Applicant were to specify the polypeptide that corresponds to the amino acids in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

25 Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 2-7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated

by Ye et al. [Biophysical Journal Abstracts, Vol. 80 (number 1): p. 225a, January 2001], Gellens et al. [Accession#: M77235, 1992], and Rogart et al. [Accession#: M27902, 1989]. Ye et al. teach hH1b polypeptides with specific mutations and

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can be used to deduce the polynucleotide sequence of SEQ ID No. 1, thus meeting the limitations of claims 2-7 and 9. Gallens et al. teach a polynucleotide sequence that is 99.2% homologous to SEQ ID No. 1, thus meeting the limitations of claims 2, 3, 5, 6, and 9. Rogart et al. teach a polynucleotide sequence that has at least 20 contiguous polynucleotides of SEQ ID No. 1 and

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encodes amino acid 558, thus meeting the limitations of claim 7.

Conclusion

NO CLAIM IS ALLOWED.

20

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **J. Jason Galvez, Ph.D.** whose telephone number is **571-272-2935**. The examiner can normally be reached Monday through Friday 9 AM to 5 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback, Ph.D.** can be

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reached at **571-272-0887**.

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The fax phone number for the organization where this application or proceeding is assigned is **703-872-9306**. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

JJG
9/01/2004


JANET ANDRES
PRIMARY EXAMINER